Doc Code: AP.PRE.REQ

PTO/SB/33 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
P35365.03(1737.3390005)

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed name _____

Application Number	Filed
10/772,101	February 4, 2004
First Named Inventor	
Jacques SEGUIN	
Art Unit	**Examiner**
3774	Ann M. SCHILLINGER

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☐ attorney or agent of record.
Registration number _____.

☒ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 63,429

Signature

C. Matthew Rozier
Typed or printed name

(202) 371-2600
Telephone number

October 12, 2010
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

1269362

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Mail Stop AF

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No.: 6184
SEGUIN *et al.*	Art Unit: 3774
Appl. No.: 10/772,101	Examiner: Schillinger, Ann M.
Filed: February 4, 2004	Atty. Docket: P35365.03(1737.3390005)
For: **Prosthetic Valve For Transluminal Delivery**	

Arguments to Accompany the Pre-Appeal Brief Request for Review

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

The following Arguments, in five (5) or less total pages, are an attachment to the Pre-Appeal Brief Request for Review (Form PTO/SB/33). A Notice of Appeal is filed concurrently herewith.

Arguments

As of the final Office Action issued on June 10, 2010, claims 150-153, 155-163, and 165-170 stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,957,949 to Leonhardt et al. ("Leonhardt") in view of U.S. Patent No. 6,305,436 to Andersen et al. ("Andersen"). Claims 154 and 164 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Leonhardt in view of U.S. Patent No. 5,104,404 to Wolff ("Wolff"). These § 103 rejections are legally and factually deficient for at least the following reasons.

*A. **The § 103 combination is improper because neither Leonhardt nor Andersen disclose or suggest extending a replacement valve past the coronary ostia, and because one of ordinary skill in the art would not have arbitrarily modified Leonhardt based on the disclosure of Andersen***

The final Office Action states that Leonhardt discloses all the features of independent claims 150, 160, and 170 except for the length of the valve support, that is, that the valve support has an axial length sufficient to extend past a patient's coronary ostia. Final Office Action, p. 4. The Office Action further states that Andersen teaches a stent, where the stent's length may be varied to give the stent the length needed to properly support any damaged, surrounding tissue. *Id.* According to the Examiner, it would have been obvious to one having ordinary skill in the art to adjust the length of the stent to extend from the annulus into the ascending aorta "in order to construct the stent to properly support the damaged tissue in the area where the prosthetic valve is being implanted." Final Office Action, p. 5. For at least the reasons detailed below, this finding constitutes clear error.

Leonhardt discloses a valve stent 20 that is implanted at the location of the mitral valve, the aortic valve, or in the aorta. Leonhardt, col. 5, ll. 41-42; col. 9, l. 63 - col. 10, l. 30; Figs. 2, 3, and 9D. Valve stent 20 is configured to conform to the tissue immediately around the location of the mitral valve and/or aortic valve, or to bond to the aorta. Leonhardt, col. 5, ll. 48-52; col. 9, l. 63 - col. 10, l. 30. As recognized by the Examiner, the valve replacement stent disclosed in Leonhardt would not be of sufficient length to implant in the aortic valve annulus and also extend into the ascending aorta.

Andersen discloses a stent for providing reinforcement to the lumen of a peristaltic organ. Andersen, col. 1, ll. 61-62. Specifically, Andersen contemplates the use of such a stent in an esophagus. Andersen, col. 6, ll. 50-53; Fig. 2 - Fig. 3e. Andersen further discloses that the stents described therein can be formed into a vascular valve, wherein the wire stent is formed with a large diameter end and a small diameter end, and wherein the large diameter end is anchored in a body passage and the smaller diameter end functions as a valve. '436 patent, col. 14, l. 56 - col. 15, l. 12.

The Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art. *In re Piasecki,* 745 F.2d 1468, 1471-73, 223 U.S.P.Q. 785, 787-88 (Fed. Cir. 1984). "Rejections on obviousness cannot be sustained by merely conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the

legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) quoting *In re Kahn,* 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329, 1336 (Fed. Cir. 2006).

Obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. *In re Kahn*, 441 F.3d 977, 986 (Fed. Cir. 2006); *see also* MPEP 2143.01. However, to reject a claim based on this rationale, the Examiner must articulate a finding that there was some reason to combine or modify the teachings of the prior art, and a finding that there was a reasonable expectation of success. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art. *See* "Examination Guidelines for Determining Obviousness under 35 U.S.C. § 103 in view of the Supreme Court decision in KSR International v. Teleflex Inc.", *Fed. Reg.* 72:57526-57535, 57534 (October 10, 2007), hereinafter "Examination Guidelines." To this end, if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Here, the Examiner's assertion that one of ordinary skill in the art would have adjusted the length of the Leonhardt valve stent to extend from a native annulus past the coronary ostia is both conclusory and unsupported by the disclosure of the cited references. Indeed, Andersen provides no teaching to extend the length of the Leonhardt valve stent past the patient's coronary ostia. Leonhardt teaches a valve stent 20 that conforms to the tissue immediately around the location of the mitral valve and/or aortic valve, or to bond to the aorta. Leonhardt, col. 5, ll. 48-52; col. 9, l. 63 - col. 10, l. 30. Leonhardt discloses that close conformance to the native valve allows the valve to be securely held in place against fluid flow in the vessel or natural valve position. Leonhardt, col. 5, ll. 2-10; col. 53-65. Thus, Leonhardt uses a particular anchoring method, and the construction of the Leonhardt valve stent is designed to achieve that anchoring method. The only portion of Andersen that discusses elongating a stent is directed to an esophageal stent, stating only that the stent can be tailored to a patients needs. Andersen, col. 8, ll. 11-19. However, in the context of esophageal stents, the only patient-specific needs discussed by Andersen are exerting force against a lumen wall to prevent growth into the lumen or to provide reinforcement to a selected region of a body lumen. Andersen, col. 2, ll. 15-36.

Presented with the disclosure of Andersen, one of ordinary skill in the art would not have modified the valve stent of Leonhardt such that the valve stent had a length sufficient to extend from the native annulus past the coronary ostia of a patient. As discussed above, Andersen

merely discloses altering the length of a stent to conform to "patient needs," and provides no teaching or motivation to extend a heart valve above the coronary ostia. Indeed, absent some additional reason to extend the length of a stent, one of ordinary skill in the art would seek to keep a replacement heart valve as compact as possible while still providing the required anchoring and valve functions. Because the valve stent of Leonhardt is secured by closely conforming to the native annulus, one of ordinary skill in the art would have no reason to add additional material, and therefore cost, labor, and complexity, to the valve stent of Leonhardt. Furthermore, as recognized by Leonhardt, minimizing the weight of a replacement valve is generally an advantage. Leonhardt, col. 2, ll. 57-64. Indiscriminately extending the valve stent of Leonhardt would increase the weight of the Leonhardt valve stent, which would be undesirable absent some further recognized advantage to extending the length of the valve stent. Accordingly, one of ordinary skill in the art would not have sought to modify the valve stent of Leonhardt based on the disclosure of Andersen.

B. The § 103 combination is improper as rendering the primary reference unsuitable for its intended purpose

Furthermore, altering the stent of Leonhardt in view of Andersen would render the valve stent of Leonhardt unsuitable for its intended purpose of securely anchoring a replacement heart valve in a native annuulus. The stent 20 of Leonhardt is configured to conform to the tissue immediately around the location of a native valve annulus in order to sealingly engage the tissue of the native valve annulus. Leonhardt, col. 5, ll. 45-51; col. 6, ll. 17-22. Extending stent 20 of Leonhardt based on the disclosure of Andersen would result in a stent that does not conform to the tissue immediately around the native valve annulus. A prosthetic heart valve must be securely anchored to remain in position during operation. Thus, if the teachings of Leonhardt were modified to include an elongated stent as disclosed by Andersen, one of skill in the art would not have a reasonable expectation of success in securing the resulting replacement valve in position in the body. A lack of secure fixation would render Leonhardt unsuitable for its intended use of heart valve replacement.

Leonhardt further describes that stent 26 may be coated with a layer of PTFE, which is an impermeable material designed to reduce the risk of blood clotting and corrosion. Leonhardt, col. 5, ll. 3-7. If the valve stent of Leonhardt was lengthened as suggested by the Examiner, the impermeable PTFE sheath would block, or at least significantly impede, blood flow to the patient's coronary arteries. Such blockage or even impedance would jeopardize all heart function

in the patient. Because such a modification would risk the life of the patient, rendering the valve stent of Leonhardt unsuitable for its intended use, one of ordinary skill in the art would not have modified Leonhardt in view of the Andersen disclosure.

C. Conclusion

For at least the foregoing reasons, claims 150-153, 155-163, and 165-170 are not rendered obvious by the combination of Leonhardt and Andersen. Claims 154 and 164 depend from and add features to claims 150 and 160, respectively, and are therefore patentable for at least the same reasons as those claims. Wolff, which was applied in rejections of claims 154 and 164, fails to remedy the deficiencies of Leonhardt and Andersen for at least the reasons described in pages 11-12 of the Amendment and Reply filed on February 12, 2010. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections of claims 150-170 under 35 U.S.C. § 103(a).

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 01-2525.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

C. Matthew Rozier
Attorney for Applicants
Registration No. 63,429

Date: October 12, 2010

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600